

IN THE CLAIMS

Please substitute the following claim set for that currently of record.

1. (Currently amended) A method of assessing cancer in a body sample of a human suspected of ~~having~~ having a cancer, comprising the steps of:
determining presence of a non-synonymous, intragenic mutation in a PIK3CA coding sequence in the body sample, wherein a wild-type PIK3CA coding sequence comprises the sequence shown in SEQ ID NO:2;
identifying the human as likely to have cancer if the presence of a non-synonymous, intragenic mutation in PIK3CA coding sequence is determined in the body sample.
2. (Original) The method of claim 1 wherein the body sample is a first tissue that is suspected of being neoplastic, and the method further comprises the steps of:
testing a second tissue that is not suspected of being neoplastic for the presence of the non-synonymous mutation, wherein the first and second tissue are isolated from the human;
identifying the non-synonymous, intragenic mutation as somatic if said mutation is absent in the second tissue.
3. (Original) The method of claim 1 wherein the non-synonymous, intragenic mutation is in exon 9 (SEQ ID NO: 4).
4. (Original) The method of claim 1 wherein the non-synonymous, intragenic mutation is in exon 20 (SEQ ID NO: 5).
5. (Currently amended) The method of claim 1 wherein the non-synonymous, intragenic mutation is in PIK3CA's helical domain (~~##~~ nucleotides 1567-2124 of SEQ ID NO: 2).
6. (Currently amended) The method of claim 1 wherein the non-synonymous, intragenic mutation is in PIK3CA's kinase domain (~~##~~ nucleotides 2095-3096 of SEQ ID NO: 2).
7. (Currently amended) The method of claim 1 wherein the non-synonymous, intragenic mutation is in PIK3CA's P85BD domain (~~##~~ nucleotides 103-335 of SEQ ID NO: 2).

8. (Original) The method of claim 1 wherein the body sample is colorectal tissue.
9. (Original) The method of claim 1 wherein the body sample is brain tissue.
10. (Original) The method of claim 1 wherein the body sample is gastric tissue.
11. (Original) The method of claim 1 wherein the body sample is breast tissue.
12. (Original) The method of claim 1 wherein the body sample is lung tissue.
13. (Original) The method of claim 1 wherein the body sample is blood, serum, or plasma.
14. (Original) The method of claim 1 wherein the body sample is sputum.
15. (Original) The method of claim 1 wherein the body sample is saliva.
16. (Original) The method of claim 1 wherein the body sample is urine.
17. (Original) The method of claim 1 wherein the body sample is stool.
18. (Original) The method of claim 1 wherein the body sample is nipple aspirate.
19. (Original) The method of claim 1 wherein PIK3CA exons consisting of 9 and 20 are tested to determine a non-synonymous mutation.
20. (Original) The method of claim 1 wherein PIK3CA exons comprising 9 and 20 are tested to determine a non-synonymous mutation.
21. (Original) The method of claim 1 wherein the non-synonymous, intragenic mutation is a substitution mutation.
22. (Original) The method of claim 1 wherein the non-synonymous, intragenic mutation is G1624A.
23. (Original) The method of claim 1 wherein the non-synonymous, intragenic mutation is G1633A.
24. (Original) The method of claim 1 wherein the non-synonymous, intragenic mutation is C1636A.
25. (Original) The method of claim 1 wherein the non-synonymous, intragenic mutation is A3140G.
26. (Original) The method of claim 1 wherein the body sample is tested for mutations at nucleotide positions 1624, 1633, 1636, and 3140 of PIK3CA coding sequence.
27. (Original) The method of claim 1 wherein the body sample is tested for mutations G1624A, G1633A, C1636A, and A3140G.

28. (Original) The method of claim 21 wherein the body sample is further tested for mutations G113A, T1258C, G3129T, and C3139T.

29. (Original) The method of claim 27 wherein the body sample is further tested for mutation G2702T.

30. (Original) The method of claim 1 wherein the non-synonymous, intragenic mutation is a deletion mutation.

31-65. (Cancelled)

66. (New) A method of characterizing a cancer in a body sample of a human, comprising the steps of:

testing the body sample to determine the presence of a non-synonymous, intragenic mutation in a PIK3CA coding sequence in the body sample, wherein a wild-type PIK3CA coding sequence comprises the sequence shown in SEQ ID NO:2.

67. (New) The method of claim 66 wherein the body sample is a first tissue that is suspected of being neoplastic, and the method further comprises the steps of:
testing a second tissue that is not suspected of being neoplastic for the presence of the non-synonymous mutation, wherein the first and second tissue are isolated from the human;

identifying the non-synonymous, intragenic mutation as somatic if said mutation is absent in the second tissue.

68. (New) The method of claim 66 further comprising:

identifying the human as likely to have cancer if a non-synonymous intragenic mutation in PIK3CA coding sequence is determined present in the body sample.

69. (New) The method of claim 66 further comprising:

prescribing a therapeutic regimen based on the presence of the non-synonymous, intragenic mutation.

70. (New) The method of claim 66 wherein progression of disease is followed by the testing of the body sample.

71. (New) The method of claim 66 wherein the non-synonymous, intragenic mutation is in exon 9 (SEQ ID NO: 4).

72. (New) The method of claim 66 wherein the non-synonymous, intragenic mutation is in exon 20 (SEQ ID NO: 5).

73. (New) The method of claim 66 wherein the non-synonymous, intragenic mutation is in PIK3CA's helical domain (nucleotides 1567-2124 of SEQ ID NO: 2).
74. (New) The method of claim 66 wherein the non-synonymous, intragenic mutation is in PIK3CA's kinase domain (nucleotides 2095-3096 of SEQ ID NO: 2).
75. (New) The method of claim 66 wherein the non-synonymous, intragenic mutation is in PIK3CA's P85BD domain (nucleotides 103-335 of SEQ ID NO: 2).
76. (New) The method of claim 66 wherein the body sample is colorectal tissue.
77. (New) The method of claim 66 wherein the body sample is brain tissue.
78. (New) The method of claim 66 wherein the body sample is gastric tissue.
79. (New) The method of claim 66 wherein the body sample is breast tissue.
80. (New) The method of claim 66 wherein the body sample is lung tissue.
81. (New) The method of claim 66 wherein the body sample is blood, serum, or plasma.
82. (New) The method of claim 66 wherein the body sample is sputum.
83. (New) The method of claim 66 wherein the body sample is saliva.
84. (New) The method of claim 66 wherein the body sample is urine.
85. (New) The method of claim 66 wherein the body sample is stool.
86. (New) The method of claim 66 wherein the body sample is nipple aspirate.
87. (New) The method of claim 66 wherein PIK3CA exons consisting of 9 and 20 are tested to determine a non-synonymous mutation.
88. (New) The method of claim 66 wherein PIK3CA exons comprising 9 and 20 are tested to determine a non-synonymous mutation.
89. (New) The method of claim 66 wherein the non-synonymous, intragenic mutation is a substitution mutation.
90. (New) The method of claim 66 wherein the non-synonymous, intragenic mutation is G1624A.
91. (New) The method of claim 66 wherein the non-synonymous, intragenic mutation is G1633A.
92. (New) The method of claim 66 wherein the non-synonymous, intragenic mutation is C1636A.
93. (New) The method of claim 66 wherein the non-synonymous, intragenic mutation is A3140G.

94. (New) The method of claim 66 wherein the body sample is tested for mutations at nucleotide positions 1624, 1633, 1636, and 3140 of PIK3CA coding sequence.
95. (New) The method of claim 66 wherein the body sample is tested for mutations G1624A, G1633A, and A3140G.
96. (New) The method of claim 95 wherein the body sample is further tested for mutations C1636A, G113A, T1258C, G3129T, and C3139T.
97. (New) The method of claim 96 wherein the body sample is further tested for mutation G2702T.
98. (New) The method of claim 66 wherein the non-synonymous, intragenic mutation is a deletion mutation.